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10/501,409	07/15/2004	Kenji Okada	YMOR:330	9556

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EXAMINER	
RAMILLANO, LORE JANET	
ART UNIT	**PAPER NUMBER**
1743	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,409	OKADA ET AL.	
	Examiner	Art Unit	
	Lore Ramillano	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. In applicant's reply filed on 4/12/07, applicant amended claims 1, 7, 10, and 13; and added new claims 14-19. Claims 1-19 are pending and under examination in the application.

2. Applicant should also note that examiner unintentionally cited the incorrect basis for the Braynin rejection in the prior Office Action (filed 1/16/07) because Braynin is a 102(b) type reference and not a 102(e) type reference. Examiner regretfully apologizes for the error and has changed the Braynin rejection from a 102(e) to a 102(b) rejection, as indicated in paragraph 10 below.

Claim Objections

3. The objection to claim 7 is withdrawn.

Claim Rejections - 35 USC § 112

4. The rejection of claims 1-13 is rejected under 35 U.S.C. 112, second paragraph, is withdrawn. In light of applicant's new claims, new rejections follow.

5. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 is rejected because claiming the flow of the liquid specimen does not structurally define applicant's invention.

Drawings

6. The objection to the drawings under 37 CFR 1.83(a) is withdrawn.

Prior art rejections

7. The 102(e) rejection over Valencia is withdrawn. The rejections over Werner; Werner in view of Valencia; and Braynin are maintained. The rejections are amended due to the amended claim language and additional new claims.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. **Claims 1-6, 8-10, and 13-19** are rejected under 35 U.S.C. 102(e) as being anticipated by Werner et al. ("Werner," US 7083920).

Werner discloses an optical bio-disc comprising: a channel (i.e. 128, Fig. 4), therein extending from an injection port (i.e. 122, Fig. 3D) toward an outer periphery and the analysis disk rotatable about an axis to cause a liquid specimen injected into the channel from the injection port to flow through an analysis area (i.e. 140, Fig. 4) located midway in the channel with respect to a radially outer end portion of the channel, and a water absorbing member is located in the end portion of the channel (i.e. nitrocellulose material of 140 is positioned in the outer end portion of the channel, column 13, lines 7-16).

Werner further discloses a reagent reactive with a constituent of the liquid specimen in the analysis area (i.e. column 4, lines 10-21); a water absorbing material composed of a porous

material, a blood coagulating agent (i.e. glass) for coagulating the liquid specimen and is bottlenecked (i.e. column 6, line 67 to column 7, line 3; Fig. 4); a portion of the channel is coated with a hydrophobic material (i.e. column 13, lines 17-25); a channel that includes a plurality of channels (i.e. 130 and 132, Fig. 4), which are connected to each other at the outer end portions; and an optical detector (i.e. 158, Fig. 3B).

In figures 2A-4, Werner further discloses a plurality of channels placed equidistantly from each other; the outer end portion of the channel is adjacent to a terminal end of the channel, and the terminal end of the channel is positioned opposite to the injection port; and the channel extends from the injection port to the water absorbing member.

10. **Claims 1-7 and 9-19** are rejected under 35 U.S.C. 102(b) as being anticipated by Braynin et al. ("Braynin," US Pub. No. 2003/0219713).

In Figs. 1-7, Braynin discloses an optical bio-disc comprising: a channel, which extends from an injection port (i.e. 22) toward an outer periphery and rotatable about an axis to cause a liquid specimen injected into the channel from the injection port to flow through an analysis area (i.e. column 8, lines 36-55) located midway in the channel to a radially outer end portion of the channel, and a water absorbing member is located in the end portion of the channel (i.e. flow path is made of hydrophilic material, column 7, lines 19-31).

Braynin further discloses in Figs. 1-7, a reagent reactive with a constituent of the liquid specimen in the analysis area (i.e. i.e. column 8, lines 36-55); a water absorbing material composed of a porous material, a blood coagulating agent (i.e. column 7, lines 19-31) for coagulating the liquid specimen; a portion of the channel is coated with a hydrophobic material (i.e. column 7, lines 19-31); a channel that includes a plurality of channels (i.e. channels connected by annual passage, column 8, lines 36-55), which are connected to each other at the

outer end portions; a valve (i.e. column 8, lines 30-35) that regulates the flow of the sample through the channels ([0313]); having an outer end portion that has a greater width than a portion of the channel radially inward of the outer end portion (column 6, line 64 to column 7, line 2); and an optical detector (19).

In figure 1, Braynin further discloses a plurality of channels placed equidistantly from each other; the outer end portion of the channel is adjacent to a terminal end of the channel, and the terminal end of the channel is positioned opposite to the injection port; and the channel extends from the injection port to the water absorbing member.

Claim Rejections - 35 USC § 103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Werner.

Werner does not specifically disclose having an outer end portion that has a greater width than a portion of the channel radially inward of the outer end portion.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Werner by having an outer end portion that has a greater width than a portion of the channel radially inward of the outer end portion because it would be desirable to provide a chamber for overflow.

13. **Claims 11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Werner in view of Valencia et al. ("Valencia," US Pub. No. 2003/0219713).

The disclosure of Werner is disclosed above. Werner does not specifically disclose having a valve.

Valencia discloses an optical bio-disc comprising: a channel (i.e. 128, Fig. 4), which extends from an injection port (i.e. 122, Fig. 3D) toward an outer periphery and rotatable about an axis to cause a liquid specimen injected into the channel from the injection port to flow through an analysis area (i.e. 140, Fig. 4) located midway in the channel to a radially outer end portion of the channel. Valencia further discloses an optical bio-disc, which comprises a valve (i.e. 310) that regulates the flow of the sample through the channels ([0313]).

Werner and Valencia are analogous art because they are from the same field of endeavor, biological assays and diagnostic assays and, in particular, to such assays conducted on optical bio-discs. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Werner with the valve limitation of Valencia as stated above, because it would be desirable to have a structural means to regulate the flow of the sample through the channels.

Response to Arguments

14. Applicant's arguments with respect to the 102(e) rejection over Werner and 102(b) rejection over Braynin, filed 4/12/07, have been fully considered but they are not persuasive.

In response to applicant's argument that Werner fails to disclose or suggest "a water absorbing member" which is "located in the outer end portion of the channel", examiner disagrees. As stated above in paragraph 8 above, Werner discloses a water absorbing member located in the end portion of the channel (i.e. nitrocellulose material of 140 is positioned in the outer end portion of the channel, column 13, lines 7-16).

In response to applicant's argument that Braynin fails to disclose or suggest "a water absorbing member" which is "located in the outer end portion of the channel", examiner disagrees. As stated above in paragraph 9 above, Braynin discloses a water absorbing member

located in the end portion of the channel (i.e. flow path is made of hydrophilic material, column 7, lines 19-31). Braynin's hydrophilic surface properly reads on applicant's water absorbing member because hydrophilic does mean water soluble.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available

through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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